

REMARKS

The Office Action of July 1, 2007, has been received and reviewed. Claims 19-24 are currently pending in the application. Claims 19-24 are under consideration. Claims 21 and 22 stand rejected. Claim 23 stands objected to. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 21 and 22 stand rejected under 35 U.S.C. § 112, first paragraph as assertedly failing to comply with the written description requirement. Specifically, it was asserted that the phrase “a means for inducing activation of the NF- κ B pathway, wherein the means is inhibitable by said ABIN consensus sequence protein” was not adequately disclosed in the Specification. Office Action mailed June 1, 2007, at page 5. It was further noted that while TNF, IL-1, TPA, RIP, and TRAF2 had adequate written description to be the means noted *supra*, the applicants were deemed to be not entitled to undisclosed means of inducing activation. *Id.* Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants respectfully note that 35 U.S.C. § 112, Paragraph 6 relates that

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

“The USPTO must apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application.” *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994). Under MPEP §2181(I), a claim element will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitation must use the phrase “means for” or “step for;”
- (B) the “means for” or “step for” must be modified by functional language; and
- (C) the phrase “means for” or “step for” must not be modified by sufficient structure, material, or acts for achieving the specified function.

Claim 21 is the only claim at issue which directly contains a means-plus-function element. Specifically, claim 21 recites, in part, “a means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by said ABIN consensus sequence protein.” Claim 22 thus indirectly contains this element by virtue of depending from claim 21. Prong (A) of the 3-prong test is met as the claim recites “means for.” Prong (B) of the 3-prong test is also met as the means for is modified by function language, to wit: “inducing activation of the NF-kB pathway.” Lastly, prong (C) of the 3-prong test is met as the “means for” recited in claim 1 is not modified by any structure, material, or acts for achieving the specified function. Applicants note that “wherein the means is inhibitable by said ABIN consensus sequence protein” is not a structure, material, or act for achieving the function, it only further defines the function being performed. As such, claim 21 invokes § 35 U.S.C. 112, sixth paragraph.

In rejecting claim 21, the Examiner alleges, that “because there can be many different structures/chemicals/factors other than disclosed TNF, IL-2, TPA, RIP, TRAF2, that can achieve the same effect and purpose in the method claimed, the applicants are not entitled to all of these undisclosed means of inducing activation.” Office Action mailed June 1, 2007 at Page 5. However, the Examiner’s assertion regarding the number of undisclosed means of inducing activation is in direct contravention to 35 U.S.C. § 112, sixth paragraph. As noted above, 35 U.S.C. § 112, sixth paragraph provides, in part, that “such claims shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” As such, the “means” recited in claim 21 cannot be construed as covering “all of these undisclosed means of inducing activation” as the means must be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Further, the MPEP at § 2163 (II)(3)(a) indicates that “A means- (or step) plus-function claim is adequately described under 35 U.S.C. § 112, paragraph 1, if the written description adequately links or associates adequately described particular structure, material or acts to the function recited in a means- (or step) plus function limitation.”

The Examiner acknowledges that TNF, IL-2, TPA, RIP, and TRAF2 are adequately disclosed means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by said ABIN consensus sequence protein. Office Action mailed June 1, 2007 at Pages 3 (see

allowable claim 19) and 7 (see objection to claim 23, which remedies the asserted lack of written description of claim 21 by specifically reciting TNF, IL-2, TPA, RIP, and TRAF2). Thus, the specification adequately links described material (e.g., TNF, IL-2, TPA, RIP, and TRAF2) to the function recited in the means-plus-function element. Consequently, applicants respectfully submit the claim 21 meets the written description requirement for a means-plus function claim as directed by MPEP § 2163(II)(3)(a).

In addition, applicants provide, in conjunction with the response, a non-executed copy of the forthcoming Declaration of Rudi Bayaert. Therein it will be declared that “[a] person skilled in the art would find adequate written description of a means for inducing activation of the NF- κ B pathway, wherein the means is inhibitable by an ABIN consensus sequence protein as, e.g., TNF, IL-2, TPA, RIP, and TRAF2 are described in the patent application as being capable of performing that function.”

In view of at least the foregoing, claim 21 must be considered under 35 U.S.C. § 112, paragraph 6, and applicants respectfully submit that the specification provides adequate written description of a means for inducing activation of the NF- κ B pathway, wherein the means is inhibitable by said ABIN consensus sequence protein. Consequently, applicants respectfully request withdrawal of the rejection of claim 21 under 35 U.S.C., first paragraph, and reconsideration of same.

In addition, applicants respectfully submit that adequate written description exists for claim 22, *inter alia*, as claim 22 depends from adequately described claim 21. Consequently, applicants respectfully request withdrawal of the rejection of claim 22 under 35 U.S.C., first paragraph, and reconsideration of same.

Rejections under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 21 and 22 stand rejected under 35 U.S.C. § 112, first paragraph as assertedly failing to comply with the enablement requirement. Specifically, it was asserted that

[T]he specification, while being enabling for a method of screening a compound for its ability to activate or suppress ABIN when TNF, IL-1, TAP, RIP, or TRAF2 are administered to the cell line to induce activation of the NF- κ B pathway, does not reasonably provide enablement for

administered to the cell line any means for inducing activation of the NF-kB pathway.” Office Action mailed June 1, 2007, pat page 5.

Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants note that:

If a “means or step plus function” limitation recited in a claim is not supported by corresponding structure, material or acts in the specification disclosure, the following rejections should be considered . . . under 35 U.S.C. 112, first paragraph, as not being supported by an enabling disclosure because the person skilled in the art would not know how to make and use the invention without a description of elements to perform the function. MPEP § 2185.

Applicants respectfully submit that the instance in which a means plus function claim may be rejected for lack of enablement, as defined above, does not apply to the instant claims. Specifically, the means recited in claim 21 is directly supported by corresponding material in the specification; *e.g.*, TNF, IL-2, TPA, RIP, and TRAF2. The Examiner acknowledges that TNF, IL-2, TPA, RIP, and TRAF2 are enabled means for inducing activation of the NF-kB pathway, wherein the means is inhibitible by said ABIN consensus sequence protein. Office Action mailed June 1, 2007 at Pages 3 (see allowable claim 19) and 7 (see objection to claim 23, which remedies the asserted lack of enablement in claim 21 by specifically reciting TNF, IL-2, TPA, RIP, and TRAF2). Thus, the “means or step plus function” limitation recited in claim 21 is supported by corresponding material (*e.g.*, TNF, IL-2, TPA, RIP, and TRAF2) in the specification disclosure.

In addition, applicants respectfully submit that a person skilled in the art would know how to make and use the invention as a description of elements to perform the function (*i.e.* TNF, IL-2, TPA, RIP, and TRAF2) has been provided in the specification.

Further, applicants provide, in conjunction with the response, a non-executed copy of the forthcoming Declaration of Rudi Bayaert. Therein it well be declared that “[a] person skilled in the art would know how to make and use the invention of claims 21 and 22 as TNF, IL-2, TPA, RIP, and TRAF2 are all described in the specification in such a way as to indicate their ability to perform the function of a means for inducing activation of the NF-kB pathway, wherein the means is inhibitible by an ABIN consensus sequence protein.”

In addition to the foregoing, applicants respectfully submit that requiring applicants to provide extra description and enablement for any and all means directly contravenes the purpose of 35 U.S.C. § 112, paragraph 6, as provided by the statute and interpreted by the Federal Circuit; to wit:

All one needs to do in order to obtain the benefit of that claiming device [(means-plus function claims)] is to recite some structure corresponding to the means in the specification, as the statute states, so that one can readily ascertain what the claim means and comply with the particularity requirement of ¶ 2. The requirement of specific structure in § 112, ¶ 6 thus does not raise the specter of an unending disclosure of what everyone in the field knows that such a requirement in § 112, ¶ 1 would entail. Atmel Corp. v. Information Storage Devices, Inc. 198 F.3d 1374, 1382 (C.A.Fed. (Cal.),1999).

Applicants respectfully submit that requiring applicants to provide extra written description and enablement for each and every possible means would contravene the intent of congress and the direction of the courts and raise the specter of an unending disclosure of what everyone in the field knows that such a further requirement from 35 U.S.C. § 112, first paragraph, would entail. Applicants have recited structures corresponding to the means in the specification (e.g., TNF, IL-2, TPA, RIP, and TRAF2) so that one can readily ascertain what the claim means and comply with the particularity requirement of ¶ 2. Thus applicants respectfully submit that they have complied with the requirements of 35 U.S.C. § 112, first paragraph, as directed by the Federal Circuit in *Atmel*.

In view of at least the foregoing, applicants respectfully submit that claim 21 should be considered under 35 U.S.C. § 112, paragraph 6 and that the specification provides adequate enablement of a means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by said ABIN consensus sequence protein. Consequently, applicants respectfully request withdrawal of the rejection of claim 21 under 35 U.S.C., first paragraph, and reconsideration of same.

In addition, applicants respectfully submit that adequate enablement exists for claim 22, *inter alia*, as claim 22 depends from adequately enabled claim 21. Consequently, applicants respectfully request withdrawal of the rejection of claim 22 under 35 U.S.C., first paragraph, and reconsideration of same.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Daniel J. Morath, Ph.D.
Registration No. 55,896
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: September 28, 2007
DJM/djm